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COUNTY OF LOS ANGELES

Public Health

JONATHAN E. FIELDING, M.D., M.P.H.
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March 12, 2012

TO: Each Supervisor

FROM: Jonathan E. Fielding, M.D., M.P.H. *JE Fielding MD*
Director of Public Health and Health Officer

SUBJECT: **MEDICATION ASSISTED THERAPY**

On December 13, 2011, your Board approved to extend the use of Vivitrol and instructed the Director of the Department of Public Health (DPH) to report back in 90-days on policy changes needed to expand the availability of Vivitrol in public coverage programs such as Medi-Cal and on recommendations on how Vivitrol can be purchased by contract providers at the most affordable price.

Policy Changes

DPH has been working with a number of agencies to expand the availability of Vivitrol in Los Angeles County. Below are highlights of the efforts to date:

- In California, providers are required to use the electronic Treatment Authorization Request (eTAR) system in order to receive reimbursement for Vivitrol doses administered to Medi-Cal eligible patients. In collaboration with contracted programs and Alkermes, Inc., the manufacturer of Vivitrol, DPH is working with the California Department of Health Care Services to improve the process of the eTAR system for Vivitrol doses. Thus far, progress has been made in improving the processing time for eTAR submissions for LA Care and Health Net patients.
- Studies have shown that the orally administered form of naltrexone is not as successful of a treatment as Vivitrol due to the significant side effects and the lack of compliance by patients to take multiple doses daily. Currently, under the Drug Medi-Cal program, only the oral naltrexone is reimbursable. Therefore, DPH is working with the California Department of Alcohol and Drug Programs to add Vivitrol to the Drug Medi-Cal pharmaceutical formulary. The County Alcohol and Drug Program Administrators Association of California also supports this action as other counties have expressed interest to add Vivitrol to their treatment approaches. This interest is largely based on other counties seeing the success of the Los Angeles County experience.
- DPH is working with the Department of Mental Health (DMH) to include Vivitrol in treating co-occurring mental health and substance use disorders for persons in the County's Public Safety Realignment Program (under Assembly Bill 109). On February 21, 2012 DMH and DPH submitted a proposal to make an initial Vivitrol dose available to prisoners released to the County and entering

treatment for co-occurring disorders under the AB 109 program. The proposal is currently under consideration by the California Department of Corrections and Rehabilitation. The needed administrative changes may take several months to implement.

- On September 15, 2011, DPH was awarded a three-year drug court enhancement funding grant by the federal Substance Abuse and Mental Health Services Administration. On February 21, 2012, your Board approved the acceptance of this funding which makes Vivitrol available to all participants in the County's drug court treatment programs. Participants in the Co-Occurring Disorders Treatment Court and Second Chance Women's Re-Entry Treatment Court at the Antelope Valley Rehabilitation Center who have already used Vivitrol have had positive results. This funding will allow more clients access to Vivitrol.

Pricing

Currently, DPH contract providers are able to purchase Vivitrol doses for medically uninsured persons at a discounted price that is considerably less than the retail price. However, pricing under the federal Health Resources and Services Administration 340B program for federally-qualified health centers and qualified hospitals is lower. DPH is working with the Department of Health Services to explore how contract providers can access the 340B price.

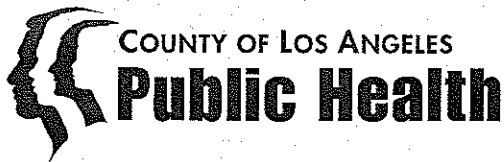
Next Steps

As instructed by the motion, DPH will provide a 12-month report to your Board on the items above and other items, including the implementation of pilot projects for use of Vivitrol and other medication-assisted treatment approaches with drinking-driver offenders and in jail and probation settings. Also included in the report will be results from the evaluation conducted by the Integrated Substance Abuse Program at the University of California, Los Angeles (UCLA). The evaluation focuses on the efficacy of Vivitrol as a cost-effective approach to improve medium- and long-term patient outcomes. The study design has passed the Institutional Review Boards at DPH and UCLA, and patient data collection has begun.

If you have any questions or would like additional information on this matter, please let me know.

JEF:wks
PH:1201:004

c: Chief Executive Officer
County Counsel
Executive Officer, Board of Supervisors



COUNTY OF LOS ANGELES
Public Health

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January 2, 2013

TO: Each Supervisor

FROM: Jonathan E. Fielding, M.D., M.P.H. *JE Fielding ms*
Director of Public Health and Health Officer

SUBJECT: **MEDICATION ASSISTED TREATMENT (VIVITROL)**

On December 13, 2011, your Board approved to extend the use of medication assisted treatment, known as Vivitrol, for clients with alcohol and opiate addictions. Your Board additionally instructed the Director of the Department of Public Health (DPH) to report back in 12 months on the efficacy of Vivitrol and recommendations for its expanded use in high-risk populations.

Efficacy of Vivitrol

In late February 2012, the Los Angeles County Evaluation System (LACES) began a one-year Vivitrol Phase II project to examine the impact on clients' use of alcohol and opiate drugs, urge to use, and side effects after their final Vivitrol dose. Phase II data will continue to be collected through February 2013. Based on preliminary data, clients' urge to drink/use went from a clinically significant score on the Urge to Drink Scale to a score within the range indicative of low risk of relapse. Additionally, the number of days a client used decreased from an average of 4.8 days in the month previous to the first Vivitrol injection to 1.2 days at follow-up (30 to 60 days after the final Vivitrol injection). Lastly, side effects decreased over time, stabilizing 12 weeks after the first injection, affecting 20 to 30 percent of clients.

Follow-up assessments with clients are conducted at 30 and 60 days after the last Vivitrol dose is provided; therefore, the time frame for completed follow-ups is between 120 days to almost one year for those who receive six doses or more. Since the study started in late February, many have not yet completed both follow-up interviews. To date, less than half of the clients who have received Vivitrol injections have completed follow-up assessments. Although the findings are preliminary, they suggest that Vivitrol effectively reduces use and the urge to use, even after cessation of treatment. Further analysis will be conducted upon completion of all data collection.

The one-year study will conclude in February 2013. Follow-up activities will take place from March to April 2013. DPH will prepare a report back to your Board with the results of the study in May 2013.

Recommendations for Expansion

DPH continues to collaborate with other organizations to increase the availability of Vivitrol in Los Angeles County. On March 1, 2012, DPH launched the Adult Drug Court Enhancement grant project to expand current Drug Court treatment services to include Vivitrol. This grant is for a period of three years and is targeted to serve approximately 27 participants per year. During year one of the project, DPH provided Vivitrol treatment services to 21 participants. To date, there have been five offenders who have successfully completed the Vivitrol treatment component and remain in the drug court treatment project.

Most of the remaining 16 participants are still participating, but have not yet completed the Vivitrol component of the drug court program. Additionally, DPH provided training on Vivitrol to all Adult Drug Court Treatment programs and court team members (i.e. judges, public defenders).

In 2012, DPH partnered with the Department of Mental Health (DMH) and the Sheriff's Department in developing a Vivitrol project for AB 109 Co-Occurring Disorders (COD) Postrelease Supervised Persons (PSPs). Under this program, PSPs with opioid dependence are screened for eligibility for Vivitrol services. The pre-release Vivitrol injection for the PSP population is being provided by DMH at County jails and is funded by the Sheriff's Department. Post-release, all subsequent outpatient injections will be provided at 12 DMH and DPH contracted COD outpatient treatment sites and funded 50 percent by DMH and 50 percent by DPH.

DPH has also partnered with the Sheriff's Department to implement in-custody treatment within the Maximizing Education Reaching Individual Transformation (MERIT) Program. The project will provide direct services to inmates, utilize co-located staff at the Twin Towers Correctional Facility's Community Transition Unit (CTU) to assist with referral and placement, and if appropriate, screen inmates scheduled for release for Vivitrol eligibility and referral for first in-custody injection and subsequent post-release injections at one of the 12 DMH or DPH contracted COD sites.

The following efforts are also underway to enhance Vivitrol accessibility:

- The California Department of Health Care Services is continuing to work with Alkermes, Inc., the manufacturer of Vivitrol, to address issues of medication cost, treatment, and service reimbursement for Medi-Cal and Medi-Cal Managed Care programs;
- DPH contracted providers are now able to purchase Vivitrol at the 340B discounted rate that is established for Federally Qualified Health Centers and qualified hospitals. The discounted rate is expected to better enable providers to incorporate the use of Vivitrol in their treatment programs; and

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- DPH and DMH are co-chairing the Drug Medi-Cal Reform Workgroup to make recommendations and reform Drug Medi-Cal formularies to allow a broader range of treatment options, including Vivitrol, for Los Angeles County residents.

DPH will continue to explore more opportunities to expand the use of Vivitrol in high-risk populations. As mentioned previously, we will report back to your Board with results on the Vivitrol study in June 2013. In the meantime, if you have any questions or would like additional information, please let me know.

JEF:tkd
PH:1201:004

c: Chief Executive Officer
County Counsel
Executive Officer, Board of Supervisors



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June 7, 2013

TO: Each Supervisor

FROM: Jonathan E. Fielding, M.D., M.P.H. *J. Fielding ms*
Director of Public Health and Health Officer

SUBJECT: **MEDICATION ASSISTED TREATMENT (VIVITROL)**

On December 13, 2011, your Board approved to extend the use of medication assisted treatment, known as Vivitrol, for clients with alcohol and opiate addictions. Your Board additionally instructed the Director of the Department of Public Health (DPH) to report back in 12 months on the efficacy of Vivitrol and recommendations for its expanded use in high-risk populations. The January 2013 report to your Board indicated that we would provide your Board with the results of the Vivitrol study. This report contains the preliminary results.

Findings

The Los Angeles County Evaluation System (LACES) study reflects the Phase II follow-up period for Vivitrol clients from February 2012 to February 2013. The study examined whether clients can maintain sobriety once they are no longer receiving Vivitrol injections. It is important to note that this is an evaluative study and not a clinical trial. Random assignment was not used to determine whether a client would receive the Vivitrol medication or a placebo.

Preliminary data from the study suggest that clients with at least one dose of Vivitrol report significant decreases in an urge to drink alcohol or the use of opioids. Results appear to suggest that Vivitrol clients' urges to drink/use remain low and that there is little danger of relapse at 30 and 60 days after their final Vivitrol injection. Of the 244 Vivitrol clients in the 30 day and 60 day follow-up groups, 212 clients (87%) reported a lower urge to drink/use and appeared to be in little danger of relapse at 30 and 60 days after their final Vivitrol injection. This decrease in urges to drink/use may indicate a continued reduction in urges to drink/use, or result in a significant delay in the return of urges after the medication is no longer administered. Additionally, preliminary analysis suggests that Vivitrol may decrease the number of days using alcohol and/or opioids. It also appears that the clients who received Vivitrol are able to maintain the reduction in days used or intoxicated after the medication is no longer administered.

Future analyses of the study will explore treatment outcomes among those receiving Vivitrol compared to similar clients who are not receiving Vivitrol.

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Recommendations for Vivitrol Expansion

DPH continues to partner with other organizations to increase the availability of Vivitrol for Los Angeles County clients. DPH has partnered with the Department of Mental Health (DMH) and the Sheriff's Department to develop a Vivitrol project for Assembly Bill 109 Co-Occurring Disorders (COD) Postrelease Supervised Persons (PSPs). Under this program, PSPs with opioid dependence are screened for eligibility for Vivitrol services. The initial Vivitrol injection is administered by DMH at the County jails and funded by the Sheriff's Department. Subsequent Vivitrol injections are then administered by DPH contracted providers.

In addition, DPH is partnering with Drug Court Treatment Teams to facilitate referrals to meet target goals for the Substance Abuse Mental Health Services Administration Drug Court Enhancement Grant.

DPH will continue to increase provider awareness of Vivitrol availability as a billable medication under Medi-Cal. This includes training providers on Medi-Cal Treatment Authorization Request (TAR) and Medi-Cal eligibility. In addition, DPH will offer Vivitrol in-service training sessions for the Drug Court Treatment Teams.

If you have any questions or would like additional information, please let me know.

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c: Chief Executive Officer
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